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MS APPEAL BRIEF - PATENTS
Docket No.: 2121-0128P
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Georges BAHR

Application No.: 08/809,650 Confirmation No.: 7849

Filed: June 13, 1997 Art Unit: 1648

For: COMPOSITIONS OF MURAMYL PEPTIDES INHIBITING THE REPLICATION OF HIV Examiner: Z. Lucas

LETTER IN RESPONSE TO NOTICE OF NON-COMPLIANCE

MS Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

May 23, 2006

Sir:

On May 17, 2006, the Examiner issued a "Notification of Non-Compliant Appeal Brief" under 37 CRF 41.37, with regard to Appellant's Appeal Brief filed on October 6, 2005 in connection with the above-captioned application.

In the Notice of Non-Compliant Appeal Brief, the Examiner states the following reasons for non-compliance.

1) The Brief does contain a statement of the status of all of the claims. Appellants respectfully disagree, and direct the Examiner's attention to page 2, item (iii) of the previously submitted brief. However, the Amended Brief has been revised to also explicitly state that the claims on appeal are "rejected" even though this must necessarily be the case.

2) The Examiner states that the brief does not contain a concise statement of each ground of rejection under 37 C.F.R.§41.37(c)(1)(vi). The Examiner notes that this section of the brief follows the "old format". Appellants note for the record that when the Appeal Brief was prepared and submitted on October 4, 2004, the MPEP had not been revised yet to include and explain the rule updates regarding appeal practice. The Federal Register final publication of the rule changes, published on August 12, 2004, Vol. 69, No. 155, did not provide an explanation as to the format that the concise statement of each ground of rejection should take. This issue was not raised by the Examiner in the communication of March 10, 2005, so Appellants did not further revise this section at that time. However, the Amended Brief submitted herewith has been revised in section vi) as detailed in MPEP §1205.02.

3) Finally, the Examiner notes that an Appendix of related proceedings should be included. The Amended Brief contains Appendix (x), stating that there are no related proceedings. In addition, Appendix (ix), stating that there is no evidence has been added.

Given the long pendency of the instant application and the fact that it has taken the USPTO over a year to review the Amended Brief of April 6, 2005 for format let alone content, Appellants kindly request immediate consideration of the instant amended Appeal Brief.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: MAY 23 2006

Respectfully submitted,

By _____

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Attachment(s)

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(i) Real Party in Interest

The real party in interest in the present application is Vacsyn, S.A. of Paris, France, as evidenced by the assignment recorded at Reel/Frame 8740/0343.

(ii) Related Appeals and Interferences

There are no related appeals or interferences.

(iii) Status of Claims

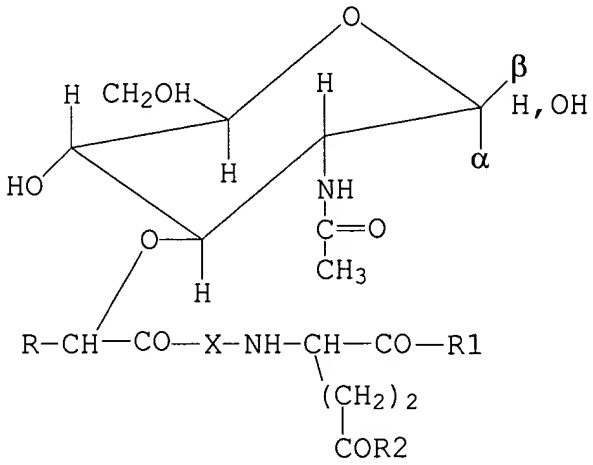
Claims 14-34 were filed with the application and new claims 35-40 were added during prosecution. Claims 14-24, 27 and 35-40 have been cancelled. Claims 25, 26 and 28-34 are rejected and stand on appeal.

(iv) Status of Amendments

No amendment was filed in response to the final rejection of the claims issued on May 4, 2004.

(v) Summary of the Claimed Subject Matter

The present invention is most broadly directed to a process for inhibiting the replication of acquired immunodeficiency retroviruses, by administering as a principal ingredient an effective amount of a muramyl peptide of formula:



in which the group R is a methyl group; X is an L-alanyl residue, and R1 is an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4, R2 is, independently of R1, either an amino or an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4 (See page 4, lines 1-6 of the specification), wherein the effective amount is also an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host (See page 5, lines 17-24 of the specification).

The present invention is further drawn processes using subgenera and specific species of the above formula, processes using the muramyl peptide in combination with another molecule capable of enhancing the anti-retroviral action of the peptide (See page 7, lines 22-28 of the specification), and to processes of treating or preventing specific diseases (See page 7, lines 17-21 of the specification).

(vi) Grounds of Rejection to be Reviewed on Appeal

(1) Whether claims 25, 26 and 28-34 are unpatentable under 35 U.S.C.§112, 1st paragraph for failing to provide adequate written description for the recitation of "as a principal ingredient".

(2) Whether claims 25, 26, 28-30 and 34 are anticipated under 35 U.S.C.§102(b) by Schreck et al.

(3) Whether claims 25, 26, 28-30 and 34 are anticipated under 35 U.S.C.§102(b) by Masihi et al.

(vii) Arguments

(1) Whether claims 25, 26 and 28-34 are unpatentable under 35 U.S.C.§112, 1st paragraph for failing to provide adequate written description for the recitation of "as a principal ingredient".

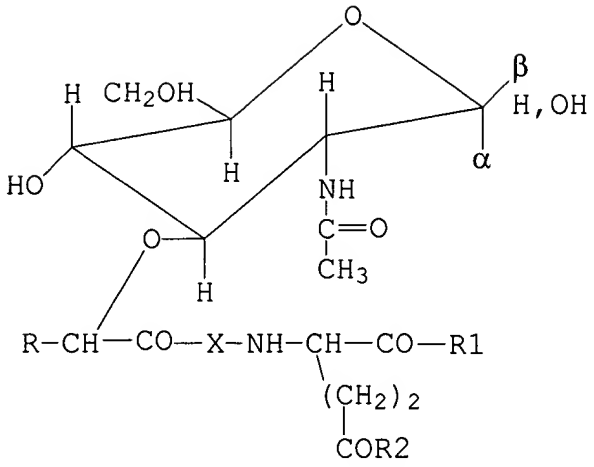
For this ground of rejection the claims stand together inasmuch as the feature that the muramyl peptide of the formula is administered "as a principal ingredient", is recited in independent claim 25 and therefore is a feature of all the dependent claims.

The Examiner asserts that recitation of the muramyl peptide in claim 1 is new matter under 35 U.S.C.§112, 1st paragraph. The Examiner notes that the specification teaches that the muramyl peptide maybe administered alone or in combination with antiviral treatments. The Examiner then asserts that "administered alone" is not the same as "as a principal ingredient" which carries the implication of additional ingredients. The Examiner states on page 3, 2nd paragraph of the Office Action of May 4, 2004 that, "'principal' equates to main, primary, major etc." and that "the specification cannot support a position that the muramyl peptide is the main composition when administered in combination with antiviral treatments...."

Appellants agree with the statement by the Examiner that "principal" may be defined as "main, primary, major etc." However, that is what precisely what the specification teaches to one skilled in the art about the muramyl peptide.

Claim 25, the only independent claim recites, in part,

> A process for inhibiting the replication of acquired immunodeficiency retroviruses..., which comprises administering as a principal ingredient...an effective amount of a muramyl peptide of formula:



in which the group R is a methyl group; X is an L-alanyl residue, and R1 is an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4, R2 is, independently of R1, either an amino or an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4, and wherein said effective amount is also an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host.

Appellants note initially that one skilled it the art would conclude that the muramyl peptide is the "principal ingredient" of any composition used in the method of claim 25 even without the explicit recitation of that feature. The method of the instant invention is clearly drawn to a therapeutic method wherein the efficacy is based on the muramyl peptide. It is evident from the specification and claims that that is the whole point of the invention. As such, the claims carry the inference that the muramyl peptide would be the principal (i.e. "main, primary, major etc.") ingredient that is administered in the claimed method. As such, it would not be new matter to recite this clearly inferred feature.

The issue of whether a feature added to the claim is adequately supported by the specification, so as to not be new matter was recently discussed in All Dental Prodx, LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 64 U.S.P.Q.2d (BNA) 1945 (Fed. Cir. 2002), wherein the Court of Appeals for the Federal Circuit (CAFC) held that,

> the failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented.

Thus, the proper determination of whether recitation in the claims that the muramyl peptide is administered "as a principal ingredient" is new matter turns on whether one skilled in the art would have recognized this feature as part of the invention. The specification at page 3, final paragraph, teaches that,

> The invention relates more particularly to the use, for the preparation of medicaments inhibiting the replication of acquired immunodeficiency retroviruses in man or those of mammals which they are capable of infecting, of a muramyl peptide of formula...

The specification further teaches on page on page 7 that,

> The therapeutic doses of the muramyl peptide (for example, Murabutide or Murametide) to be administered either alone, or in combination with antiviral treatments, particularly cytokines are between 1μg and 500μg/kg/day.

In addition, all of the experiments tested and demonstrated the inhibitory properties of muramyl peptides. For example, page 6 final paragraph, demonstrates the ability of murmayl peptides, alone, to inhibit HIV replication in primary cultures of human monocytes. The results of the experiments are shown in Table 2 and demonstrate complete inhibition of retrovirus replication with treatment at day (-1), day (0) or day (+1).

It is clear from the specification that the whole point of the invention is the therapeutic use of the muramyl peptide to inhibit retrovirus replication. It is further evident from the specification that the peptides have sufficient efficacy by themselves; however they can be used in combination with other antiviral agents. One skilled in the art would recognize upon reading the specification that the new language of "as a principal ingredient" reflects what the specification shows has been invented, i.e. the administration of the muramyl peptide as the principle (i.e. "main, primary, major etc.") ingredient, for the inhibition of acquired immunodeficiency retroviruses in man or susceptible animals. As such, recitation of "as a principle ingredient" is adequately supported by the specification, and therefore not new matter. Withdrawal of the rejection is respectfully requested.

(2) Whether claims 25, 26, 28-30 and 34 are anticipated under 35 U.S.C.§102(b) by Schreck et al.

For the second ground of rejection, the claims are separated and argued as two groups. The first group (Group 1) to be argued contains claims 25, 28-29 and 34. The second group (Group 2) contains claims 26 and 30.

a) Group 1 - Claims 25, 28-29 and 34

Claims 25, 28-29 and 34 have been rejected under 35 U.S.C. §102(b) as being anticipated by Schreck et al. In the office action of July 28, 2003, the Examiner presents the following assertions regarding the teachings of Schreck et al. (In the final office action, the Examiner maintained the rejection "for the reasons of record.)

i) The Examiner asserts that Schreck et al. refer to "murabutide" as an immunostimulant.

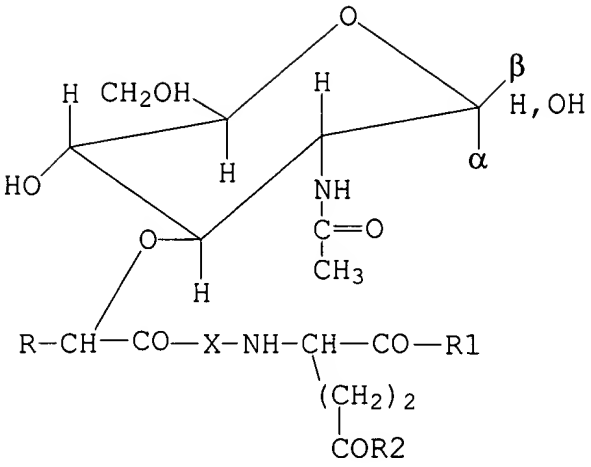
ii) The Examiner also asserts that the reference to murabutide as an adjuvant is "a matter of semantics, since the term does not exclude other descriptive terms."

iii) The Examiner asserts that the recited steps of the invention are the same steps disclosed in Schreck et al.

It is well established that,

> To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). In addition, to support a rejection for anticipation the Examiner must completely identify each and every facet of the invention. Ex parte Levy 17 USPQ2d 146 (Bd. Pat. App. & Interfer. 1990).

The instant invention as recited in independent claim 25 is directed to a process for inhibiting the replication of acquired immunodeficiency retroviruses, by administering as a principal ingredient an effective amount of a muramyl peptide of formula:



wherein the effective amount is also an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host.

There is no disclosure or suggestion in Schreck et al. that muramyl peptides can inhibit the replication of immundeficiency retroviruses. Rather, Schreck et al. teach the use of muramyl peptides as adjuvants in AIDS vaccines. Schreck et al. do not teach any specific inhibitory activity on the replication of acquired immunodeficiency retroviruses for any of the muramyl peptides assayed. Indeed throughout the experimental section of this publication no HIV-1 infected cells were used. Rather three types of cells lines were used which were human Jurket T cells, a human monocyte-macrophage cell line called Mono-Mac-8 and a mouse pre-B cell line 70Z/3.12. As indicated in the "Material and Methods" section, none of these cell lines were infected with HIV-1. Thus, with Schreck et al. the compounds were never exposed to HIV-1 and it was not possible to achieve the invention with Schreck et al., either explicitly or inherently.

With respect to points i) and ii), above and raised in the July 28, 2003 office action, Appellants respectfully note that use of the terms "immunostimulant" versus "adjuvant" is not merely a matter of semantics. The Examiner might be correct if the muramyl compounds per se were being claimed. In that case, whether a compound is

descriptively called an "immunostimulant" "an adjuvant" or is labeled by its chemical name, "muramyl peptide", would not matter for purposes of patentabililty. However, the compounds are not being claimed as the instant invention, but rather a method. As such, whether something is acting as an immunostimulant or an adjuvant is not merely a matter of semantics, i.e. the same thing with different names, but rather a defining element of the method.

The elements of claims 25, 28-29 and 34 recite the administration of an effective amount of a particular genus of muramyl peptides as a principal ingredient to inhibit immunodeficiency retroviruses. The effective amount muramyl peptide is capable of causing a 100% inhibition of replication of the retrovirus in primary cultures of monocytes of the host.

Schreck et al. fail to disclose administering the muramyl peptides disclosed therein as a principal ingredient. Appellants strongly contend that a principal ingredient cannot be interpreted to mean an adjuvant.

An "adjuvant" is a material used in conjunction with highly purified vaccines made from small molecular weight antigens, which are poor immunogens. These vaccines are poor immunogens because they lack intrinsic adjuvanicity that is usually provided by more complex natural and higher molecular weight molecules. Thus, T cell epitopes that elicit help for antibody production against the B cell epitope reside on the "adjuvant portion" of the antigen molecule and without the adjuvant portion the antigen produces a lower level of immunity. In addition, adjuvants help to provide the appropriate physical structure to the antigen so that the epitope is identified and processed by the immune system to generate an immune response. An adjuvant is a material that makes the target antigen more immunogenic to the immune system and thus helps elicit a stronger immune response to the antigen (principal ingredient). This is, with a vaccine the "principal ingredient" is the antigen.

Thus, an adjuvant cannot be considered as a principal ingredient in a vaccine, since it is the antigen *per se* that is foremost in importance in a vaccine to obtain immunity and not the adjuvant. It should be emphasized that importance is not a measure of quantity, but effect and administering muramyl peptides as a principal ingredient is not disclosed in Schreck et al.

The Examiner is further incorrect with regard to point iii) that the recited steps of the invention are the same steps disclosed in Schreck et al.

The Examiner appears to a large degree to base the rejection on the recitation in claim 29 using the instant invention "for the prevention or treatment of AIDS or related syndromes." See pages 3 and 4 of the final office action of May 4, 2004. The Examiner takes the position that the recitation of the "prevention" of AIDS as meaning that the claims encompass administering to patients who do not have HIV virus. However, "AIDS" is a disease state that may result from HIV infection. If a person does not have AIDS it does not mean that the person is also not infected with acquired immunodeficiency retrovirus. Thus, recitation in claim 29 of the prevention of AIDS does not necessarily mean that the patient is HIV-negative. On the contrary, when the limitations of claim 25, from which claim 29 depends, are read into claim 29 and from the specification it is clear that claim 29 is directed to treating or preventing AIDS in HIV infected patients. The preamble of claim 25 recites, "A process for inhibiting the replication of acquired immunodeficiency retroviruses." One cannot practice a process for inhibiting the replication of acquired immunodeficiency retroviruses unless the virus is present.

> In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). "[A] claim preamble has the import that the

> claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. See, e.g., Electro Sci. Indus. v. Dynamic Details, Inc., 307 F.3d 1343, 1348, 64 USPQ2d 1781, 1783 (Fed. Cir. 2002); Rapoport v. Dement, 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1219 (Fed. Cir. 2001); Pitney Bowes, 182 F.3d at 1306, 51 USPQ2d at 1166. *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 66 U.S.P.Q.2d (BNA) 1271 (Fed. Cir. 2003).

The feature of replicating retroviruses in the body of claim 25 finds antecedent basis in the preamble of the claim. In addition, as noted above, one cannot practice a process for inhibiting the replication of acquired immunodeficiency retroviruses unless the virus is present. Thus, the preamble of claim 25 breathes life into the meaning of the claim and the present invention actually inhibiting acquired immunodeficiency retroviruses. As such, the Examiner has incorrectly interpreted the claims and the recitation in claim 29 of preventing AIDS does not mean the treatment of patients who are not infected with HIV.

In addition, Schreck et al. fails to teach or disclose administering an effective amount of the claimed muramyl peptides of the claims 25, 28-29 and 34, wherein the effective amount is an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host. This feature is not explicitly disclosed in Schreck et al. Nor can it be inherently inferred to the reference, since as discussed above, Schreck et al. do not disclose that their muramyl peptides can inhibit the replication of immunodeficiency retroviruses, nor did they ever expose HIV-1 to the peptides.

Therefore, Appellants submit that with respect to Claims 25, 28-29 and 34, Schreck et al. cannot be said to anticipate these claims, either explicitly or inherently.

b) Group 2 - Claims 26 and 30

The invention of claim 26 is drawn to the very narrow subgenus of compounds wherein R1 and R2 are $O(CH_2)_xH$ groups. The invention of claim 30 recites the feature that the muramyl peptide is administered together with another molecule capable of enhancing the anti-retroviral action of the muramyl peptide. The arguments presented above with regard to the claims of Group 1, regarding the patentability of the invention of claims 25, 28-29 and 34 over Schreck et al. are equally applicable to claims 26 and 30, which depend from claim 25, and are hereby incorporated by reference for the sake of brevity.

However, the inventions of claims 26 and 30 are separately patentable from claims 25, 28-29 and 34, over Schreck et al. for the reasons that follow.

As noted above, the invention of claim 26 requires the administration of muramyl peptides wherein R1 and R2 are $O(CH_2)_xH$ groups. There is no disclosure in the Schreck et al. of the muramyl peptides of claim 26. As such, Schreck et al. fails to disclose each and every feature of claim 26 and Schreck et al. fails to anticipate the invention of claim 26.

Likewise for claim 30 there is no disclosure in Schreck et al. of the feature of administering another compound capable of enhancing the anti-retroviral action of the muramyl peptide with the muramyl compositions of the invention. As such, Schreck et al. fails to disclose each and every feature of claim 30 and Schreck et al. fails to anticipate the invention of claim 30.

(3) Whether claims 25, 26, 28-30 and 34 are anticipated under 35 U.S.C.§102(b) by Masihi et al.

For the third ground of rejection, the claims are separated and argued as two groups. The first group (Group 1) to be argued contains claims 25, 28-29 and 34. The second group (Group 2) contains claims 26 and 30.

a) Group 1 - Claims 25, 28-29 and 34

Claims 25, 28-29 and 34 have been further rejected for as being anticipated by Masihi et al.

The final office action makes minimal reference to Appellants' arguments of October 28, 2003, regarding Masihi et al. However, since the final office action does indicate that the rejection of the claims based on Masihi et al. is maintained for the reasons of record, Appellants address herein the rejection as stated in the office action of July 28, 2003.

Contrary to the assertion of the Examiner, the invention of Claims 25, 28-29, and 34 satisfies the requirement of novelty of 35 U.S.C. § 102(b), in view of Masihi et al. because Masihi et al. fail to disclose that the murabutide used in the reference as an adjuvant inhibits immunodeficiency retrovirus replication in man and further fails to disclose what effective amount should be administered.

Appellants also submit that for very similar reasons discussed above regarding Schreck et al., claims 25, 28-29, and 34 are not anticipated by Masihi et al. The arguments made regarding the rejection over Schreck et al. equally apply to Masihi et al. and these arguments are therefore incorporated herein by reference in order to avoid repetitiveness.

Essentially, the Examiner asserts that since a single sentence in Masihi et al. teaches that murabutide was used as an adjuvant in human clinical trials for AIDS, that claims 25, 28-29 and 34 are anticipated by this reference.

It should be specifically stated that the sole reliance by the Examiner in maintaining this rejection appears at page 397 of Masihi et al. where the following is stated:

> A nonpyrogenic butyl ester analog of MDP, murabutide, has been used as an adjuvant in human clinical trials.

First of all, it should be stressed that, as discussed above regarding Schreck et al., an adjuvant is not considered by those skilled in this art as a principal ingredient. This is not a question of semantics, as the Examiner purports, but a question of scientific terminology. See the relevant discussion in the argument regarding Schreck et al. as to the difference between an "adjuvant" and a "principal ingredient." Again, by definition, an adjuvant is a substance which, when used in combination with a specific antigen produces a higher level of immunity than that produced by the antigen alone.

Therefore, an adjuvant cannot be considered as a principal ingredient in a vaccine, since it is the antigen *per se* that is foremost in importance in a vaccine to obtain immunity and not the adjuvant.

Moreover, like Schreck et al., Masihi et al. is completely silent with respect to the results obtained from the AIDS trial. The mere statement that murabutide has been administered to a human does not imply that it has been used with success, such that HIV-1 replication was inhibited. It cannot be assumed or inferred from this sole sentence in Masihi et al. that inhibition of immunodeficiency retrovirus replication was in fact achieved.

The Supreme Court clearly stated in Eibel v Minnesota & Ontario Paper Co., "accidental results, not intended and not appreciated, do not constitute anticipation." Eibel Processing Co. v. Minnesota & Ontario Paper Co. 261 U.S. 45 (1923). The CAFC stated in In re Roberton that, "to establish inherency...extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference *and it would be so recognized by persons of ordinary skill.*" (emphasis added) In re Roberston 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999) similarly in Rosco v. Mirror Lite, the Federal Circuit held that for anticipation by inherency one skilled in the art must "read" the reference as disclosing the invention. Rosco v. Mirror Lite Co., 64 USPQ2d 1676 (Fed. Cir. 2002).

There is no way that one skilled in the art would ever read the one sentence disclosure in Masihi et al. that MDP was used as an adjuvant as inherently disclosing that an effective amount of the muramyl peptides of claim 1 was administered to a patient to inhibit the replication of immunodeficiency virus and that the amount of muramyl peptide administered was sufficient to result in 100% inhibition of HIV in primary cultures of monocytes of the host. As such, the threshold and showing for a rejection by inherency has not been met.

The above arguments regarding Schreck et al. are similarly applicable to Masihi et al. Misihi et al. also teach the use of a muramyl peptide (murabutide) as an adjuvant. While there is a single sentence in Masihi et al. that murabutide was used as an adjuvant in human clinical trials for AIDS, there is no disclosure or suggestion that the murabutide itself had any effect on replication of retroviruses.

The Examiner appears to further indicate in the final office action, that as with Schreck et al., the rejection over Masihi et al. is based on the erroneous interpretation of the claims that the instant invention encompassed treating patients, who are not infected with acquired immunodeficiency retrovirus. As discussed above, this erroneous interpretation of the invention is based on the recitation in claim 29 or "preventing" AIDS.

As discussed above, AIDS is a disease state, and lack of AIDS does not mean lack of HIV infection. Claim 29, which depends from claim 25, incorporates all of the features of claim 25. Claim 25 requires the presences of virus.

In the Office Action of July 28, 2003, the Examiner erroneously states that "well settled patent law establishes that the preamble is not given patentable weight."

The Examiner has both misinterpreted the claims and is legally incorrect in her position. As discussed above in the context of Schreck et al. and as further discussed below, the preamble is a limitation of the present claims. In addition, the disclosure of administering muramyl peptides to the culture of cells cannot be interpreted as being an inherent disclosure of prophylaxis, since as also noted below, a culture dish is not a man or animal and the present invention recites administering a "man or animal."

The Examiner's position is legally incorrect in the statement, "well settled patent law establishes that the preamble is not given patentable weight". Appellants note in this regard that the Examiner has not cited any case law in support of her position. The courts early on stated that "there is no general rule for deciding the weight given to claim preambles as positive structural recitations", In re Neugebauer et al., 51 CCPA 1138, 330 F.2d 353 (Ct. of Cust. & Pat. Apps.) 1964. The CAFC presented a thorough review of case law regarding preambles in Eaton Corp., and stated the following.

> In general, a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1784 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). "[A] claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. See, e.g., Electro Sci. Indus. v. Dynamic Details, Inc., 307 F.3d 1343, 1348, 64 USPQ2d 1781, 1783 (Fed. Cir. 2002); Rapoport v. Dement, 254 F.3d 1053, 1059, 59 USPQ2d 1215, 1219 (Fed. Cir. 2001); Pitney Bowes, 182 F.3d at 1306, 51 USPQ2d at 1166.

Thus, whether the preamble is a patentable feature of the invention must be determined on a case-by-case basis and there is no set arbitrary rule from the case law as stated by the Examiner. The present claims recite several features in the preamble, which are clearly needed to "breathe life and meaning into the claims" which provide antecedent basis for elements in the body of the claims. These feature therefore are elements of the invention. Firstly, the preamble recites "a method for inhibiting the replication of acquired immunodeficiency retroviruses in man or in...animals." Clearly a petri dish is not a man or animal. In addition, one skilled in the art would not be inhibiting the replication of acquired immunodeficiency retroviruses unless the retrovirus was present. The preamble further provides antecedent basis for the feature of "said retroviruses." "When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention." Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 66 U.S.P.Q.2d (BNA) 1271 (Fed. Cir. 2003). Thus, the preamble, which provides antecedent basis must be considered a patentable feature of the invention.

Therefore, each and every element of Claims 25, 28-29 and 34 are neither explicitly nor inherently disclosed in Masihi et al. and the rejection of the these claims as being anticipated by Masihi et al. must be withdrawn.

b) Group 2 - Claims 26 and 30

The arguments presented above regarding the third ground of rejection of the claims Group 1, regarding the patentability of the invention of claims 25, 28-29 and 34 over Masihi et al. are equally applicable to claims 26 and 30, which depend from claim 25, and are hereby incorporated by reference for the sake of brevity. In addition, the inventions of claims 26 and 30 are separately patentable from claims 25, 28-29 and 34, over Masihi et al. for the reasons that follow.

As noted above, the invention of claim 26 requires the administration of muramyl peptides wherein R1 and R2 are $O(CH_2)_xH$ groups. There is no disclosure in the Masihi et al. of the muramyl peptides of claim 26. As such, Masihi et al. fails to disclose each

and every feature of claim 26 and Masihi et al. fails to anticipate the invention of claim 26.

Likewise for claim 30 there is no disclosure in Masihi et al. of the feature of administering another compound capable of enhancing the anti-retroviral action of the muramyl peptide with the muramyl compositions of the invention, as set forth in claim 30. As such, Masihi et al. fails to disclose each and every feature of claim 30 and Masihi et al. fails to anticipate the invention of claim 30.

If the Examiner has any questions concerning this application, the Examiner is requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____

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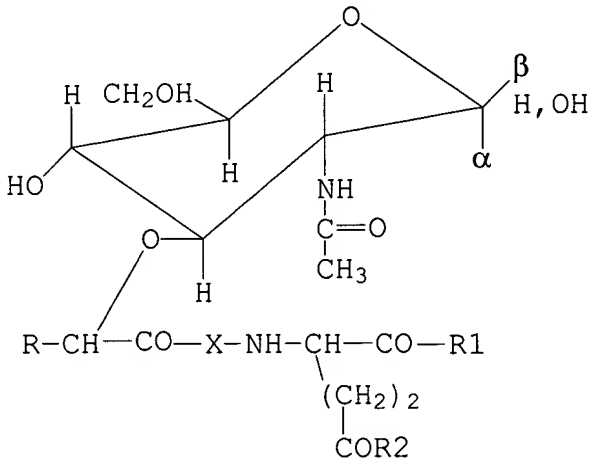
(viii) Claims Appendix

25. A process for inhibiting the replication of acquired immunodeficiency retroviruses in man or in those animals which said retroviruses are capable of infecting, which comprises administering as a principal ingredient to said man or said animals in need of such treatment an effective amount of a muramyl peptide of formula:



in which the group R is a methyl group; X is an L-alanyl residue, and R1 is an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4, R2 is, independently of R1, either an amino or an $O(CH_2)_xH$ group with x= 1, 2, 3 or 4, and wherein said effective amount is also an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host.

26. The process of claim 25, wherein both R1 and R2 are $O(CH_2)_xH$ groups.

28. The process of claim 25, wherein the muramyl peptide is Murabutide.

29. The process of claim 25, which is for the prevention or treatment of AIDS or related syndromes.

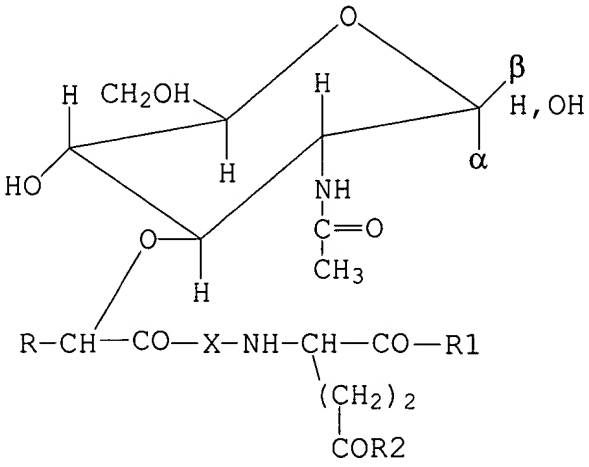
30. The process of claim 25, which comprises administering said muramyl peptide together with another molecule capable of enhancing the anti-retroviral action of said muramyl peptide.

31. The process of claim 30, wherein the other molecule is a cytokine.

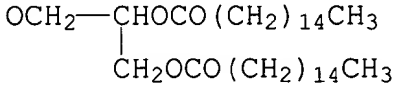
32. The process of claim 30, wherein the other molecule is GM-CSF.

33. The process of claim 30, wherein the other molecule is a protease inhibitor.

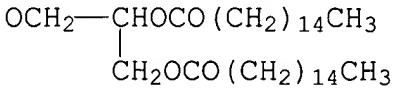
34. The process of claim 25, wherein the muramyl peptide has the formula:



in which the R is methyl; X is an L-alanyl residue or L-threonyl residue, and R1 is an $O(CH_2)_xH$ group with X = 1, 2, 3, or 4, R2 is, independently of R1, either an amino or an $O(CH_2)_xH$ group with X = 1, 2, 3, or 4 or group:



it being understood that, when X is an L-alanyl residue, at least one of these two groups R1 and R2 is an $O(CH_2)_xH$ group as defined above, and that R2 cannot be a group:



and wherein said effective amount is also an amount that is capable of causing a 100% inhibition of the replication of said retroviruses in primary cultures of monocytes of the host.

(ix) Evidence Appendix

NONE

(x) Related Proceedings Appendix

NONE